

### **Remarks/Arguments**

The foregoing amendments to the claims are of a formal nature, and do not add new matter. Claims 119-138 were pending in this application and were rejected on various grounds. Claims 119-122, 126-128 and 132-134 are canceled with prejudice or disclaimer for pursuing their subject matter in subsequent applications. Further, claim 123 has been amended with the functional recitation "wherein, said nucleic acid is amplified in squamous cell-type lung carcinomas or colon tumors," support for which is found in Example 170 of the instant application. The rejections to the presently pending claims are respectfully traversed.

### **Specification**

The disclosure was objected to by the Examiner for an informality which has been amended. Further, the foregoing amendments to the specification have deleted all embedded hyperlinks. Accordingly, Applicants believe that all objections to the specification have been overcome and should be withdrawn.

### **Claim Rejections – 35 USC § 112, second paragraph**

Claims 119-124, 126-128, 132, 133 and claims 125, 129-131, 134-138 are rejected under 35 U.S.C. §112, second paragraph for being indefinite.

In view of the cancellation of Claims 119-122, 126-128 and 132-134, this rejection has been obviated with respect to these claims. Further, Applicants have deleted all references to "extracellular domain," "signal sequence" etc. for clarity. Accordingly, Applicants submit that the claims are definite and respectfully request that this rejection be withdrawn.

### **Claim Rejections – 35 USC §112, 1st paragraph- written description**

Claims 119-138 were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. The Examiner noted that there was no description of the "signal sequence" as PRO290 was believed to be an intracellular protein. Further, the Examiner noted that the instant claims were genus claims drawn to a "nucleic acid encoding a polypeptide or hybridizes to a sequence of SEQ ID 32" wherein the nucleic acid were defined by sequence alone.

In view of the cancellation of claims 119-122, 126-128 and 132-134 and the deletion of references to the "signal sequence" and the "extracellular domain" in the remaining claims, these rejections are obviated.

Further, claim 123 has been amended with the functional recitation "wherein, said nucleic acid is amplified in squamous cell-type lung carcinomas or colon tumors," and Applicants submit that, based on the instant disclosure, the skilled artisan would reasonably accept that Applicants had possession of the instantly claimed subject matter at the time of the effective date of filing.

Hence, Applicants respectfully request that this rejection be withdrawn.

#### **Claim Rejections - 35 USC § 112, first paragraph-enablement**

Claims 119-128 and 132-138 were rejected under 35 U.S.C. §112, first paragraph "because the specification, while being enabling for a nucleic acid of SEQ ID NO:33, does not reasonably provide enablement for other nucleic acids".

Again, this rejection is moot for Claims 119-122, 126-128 and 132-134 in view of their cancellation. Further, in view of the deletion of references to the "signal sequence" and the "extracellular domain" in the remaining claims and addition of the functional recitation "wherein, said nucleic acid is amplified in squamous cell-type lung carcinomas or colon tumors," to claim 123, Applicants believe that, based on the instant disclosure which details how to make and use nucleic acid variants (see pages 308-311) and the advanced knowledge in the art at the time of filing, one skilled in the art would know exactly what nucleic acids the instant claims encompass and would know how to make and use them for the diagnosis of squamous cell-type lung carcinomas or colon cancers without undue experimentation.

Thus, Applicants believe that these rejections under 35 U.S.C. §112, first paragraph, should be withdrawn.

#### **Priority**

Applicants rely on the gene amplification assay for patentable utility of this case. This was first disclosed in U.S. Provisional Application 60/141,037, filed June 23, 1999, priority to which has been claimed in this application. Hence, the instant application is at least entitled to an effective filing date of **June 23, 1999**.

**Claim Rejections - 35 USC § 102**

1) Claims 119-121, and 132-134 are rejected under 35 U.S.C. §102(b) as being anticipated by US 6,607,879 (dated 2003).

2) Claims 119-121, and 132-134 are rejected under 35 U.S.C. §102(b) as being anticipated by US 5,952,223 (dated September 1999).

As discussed above, the instant application is at least entitled to an effective filing date of **June 23, 1999**, and hence the above cited references are not prior art. Therefore, this rejection should be withdrawn.

3) Claims 119-123, 126, 128 are rejected under 35 U.S.C. §102(b) as being anticipated by GenBank AB011112.1 (dated 10 April 1998).

In view of the cancellation of claims 119-122, 126-128 and 132-134, this rejection is obviated for these claims. AB011112.1 discloses a sequence that is 96% similar to SEQ ID NO: 32 and hence does not read on claim 123 of the instant application which recites a sequence 99% similar to SEQ ID NO: 32 and hence, this rejection should be withdrawn.

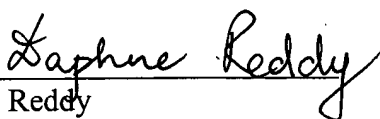
The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (**Attorney Docket No.: 39780-2730P1C49**).

Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: August 20, 2004

  
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Daphne Reddy  
Reg. No. 53,507

**HELLER EHRMAN WHITE & McAULIFFE LLP**

**Customer No. 35489**

275 Middlefield Road

Menlo Park, California 94025

Telephone: (650) 324-7000

Facsimile: (650) 324-0638

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